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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,475	02/12/2002	Susana Salceda	DEX-0313	7335

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EXAMINER	
SMITH, CAROLYN L	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,475	SALCEDA ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004 and 30 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 2/23/04 and 4/30/04, are acknowledged. Amended claims 1-5 and 8 and cancelled claims 6 and 9-17 are acknowledged.

Applicant's arguments, filed 2/23/04 and 4/30/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to compositions and methods relating to breast specific genes and proteins, whereas in contrast the elected claims are specifically directed to a nucleic acid, vector and host cell. Applicants stated in the Remarks section, filed 2/23/04, that the title has been amended, but Applicants still need to add this change in the Amended Section of their next response.

Claims herein under examination are 1-5, 7, and 8.

PATENTABLE UTILITY GUIDELINES

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

Claims Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

The rejection of claims 1-5, 7, and 8 is maintained under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

This rejection is maintained and reiterated for reasons of record.

The critical limitation of claims 1-5, 7, and 8 is the nucleotide sequence of the claimed nucleic acids, vector and host cell, SEQ ID NO: 156. The claimed nucleic acid, vector, and host cell are not supported by a specific utility, because the disclosed uses of these compositions are

not specific and are generally applicable to the breast specific polynucleotides. The specification states the polynucleotides can be used in diagnostic methods (pages 89 and 93) and monitoring breast cancer in patients (page 95). The specification summarizes general sequence uses in modern biotechnology (i.e. making pharmaceutical compositions (page 99)), but never connects the specifically elected sequence (SEQ ID NO: 156) to any particular or available utility. The above-mentioned list of possible utilities for the claimed sequence falls short of a readily available utility. These are non-specific uses that are applicable to many polynucleotides, vectors and host cells, and are not particular or specific to the polynucleotides, vectors, and host cells being claimed.

Further, these claimed polynucleotides, vectors, and host cells are not supported by a substantial utility, because no substantial utility has been established for the claimed subject matter. SEQ ID NO: 156 may indeed be a sequence found in cancerous breast tissue; however, this allegation does not adequately define a "real world" context of use. For example, basing gene expression analysis solely on Expressionist software program from GeneData Inc. (page 114) without showing actual data regarding the elected sequence does not immediately identify a real world use. While applicants have described applying Expressionist software program to propose allegations of sequences being associated with a particular type of cancer, such assertions appear to be merely allegations without support based on scientific facts regarding the elected sequence.

Applicants point to pages 113 through 115 of the specification detailing the criteria or parameters for the Expressionist program experiments that appear to be based on sound scientific reasoning. However, these pages provide no particular factual support or scientific data

regarding elected sequence of SEQ ID NO: 156. Therefore, the claimed polynucleotides, vectors, and host cells lack a substantial utility as these products are supported only by allegations that do not support a readily available use.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

Due to a lack of either an art recognized or alleged well established utility, the instant invention has been rejected due to also lacking the required combination of a specific, substantial, and credible utility. Although it may be credible that the polynucleotide of SEQ ID NO: 156 is only differentially expressed in cancerous breast tissue which may have substantial utility, the lack of a specific utility, as explained above, sufficiently supports this rejection.

Claim Rejections – 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6)

the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of the skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

The rejection of claims 1-5, 7, and 8 is maintained under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention.

This rejection is maintained and reiterated for reasons of record.

Without further data or sound scientific reasoning, it appears speculative whether the polynucleotide of SEQ ID NO: 156 plays a role in any of the asserted utilities as discussed above in the 35 U.S.C. § 101 rejection. Several options exist to overcome this lack of enablement issue, such as supplying additional data or other scientific reasoning that would lead one of ordinary skill in the art to be able to make and/or use the present invention.

Since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above (refer to the 35 U.S.C. § 101 rejection), one skilled in the art would not know how to use the claimed invention.

Applicants point to pages 109-115 of the specification to support the utility and enablement of the instant invention. However, it is noted that there is no specific scientific evidence relating particularly to SEQ ID NO: 156 that would lead one of skill in the art to determine that this particular sequence has utility and adequate enablement. Data showing

significant results from the Expressionist software experiments for SEQ ID NO: 156 would provide adequate support for the allegations of this sequence being a breast specific nucleic acid and would therefore nullify the 35 USC 101 and 35 USC 112, 1st paragraph, lack of enablement rejections of the instant invention.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The rejection of claims 1, 4, and 5 is maintained under 35 U.S.C. 102(a) as being anticipated by Genbank (Accession Number AF219946).

This rejection is maintained and reiterated for reasons of record.

GenBank discloses a *homo sapiens* mRNA sequence (Accession Number AF219946, residues 1358-5989) that has 100% similarity to SEQ ID NO: 156 (residues 1-4632). Thus, GenBank anticipates the limitations in claims 1, 4, and 5.

Applicants note that GenBank Accession Number AF219946 contains 7,687 nucleotides while SEQ ID NO: 156 contains 4632 nucleotides. This is acknowledged. Because claim 1 does not recite "consisting of" terminology, it is not necessary for the length of the GenBank sequence to be identical to that of SEQ ID NO: 156. Applicants have amended claim 1 to recite "consisting essentially of" terminology. Applicants state that because there is no teaching of

AF219946 relating to consisting essentially of SEQ ID NO: 156 and its utility as a diagnostic cancer marker, this reference does not anticipate the amended claims. This is found unpersuasive as the "consisting essentially of" terminology requires the prior art to have at least the sequence of SEQ ID NO: 156, which it does. Also, Applicants' arguments about the prior art needing to teach the utility of being a diagnostic cancer marker is found unpersuasive as this limitation is not stated in the claims such that its presence in the prior art is not a requirement in order to anticipate claims 1, 4, and 5.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

in Crystal Mall 1. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

July 8, 2004

Ardin H. Marschel 7/8/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER